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Shuji Miyagawa

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BIRCH STEWART KOLASCH & BIRCH  
PO BOX 747  
FALLS CHURCH, VA 22040-0747

EXAMINER

DIBRINO, MARIANNE NMN

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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com



## DETAILED ACTION

### REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, Applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claim 1, drawn to an HLA-E chimeric molecule.

II. Claim 2, drawn to a nucleic acid molecule encoding the HLA-E chimeric molecule of claim 1.

III. Claim 3, drawn to a nonhuman mammalian cell or nonhuman mammalian animal transformed by the nucleic acid sequence of claim 2. Note that the nonhuman mammalian transformed cell is not an isolated cell.

2. The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 1 of the instant application does not provide a technical feature that is distinguished over the prior art, as evidenced by Matsunami *et al* (Transplantation, 78(2), page 157, Abstract O401, July 27, 2004).

Matsunami *et al* teach HLA-E chimeric molecules that have substitutions of portions of HLA-E with portions of HLA-G1: the signal peptide of HLA-G1, and additionally point substitution(s) in the  $\alpha 1$  and  $\alpha 2$  domains, the signal peptide of HLA-G1 plus the  $\alpha 1$  and  $\alpha 2$  domains of HLA-G1, or the HLA-G1 signal peptide plus the  $\alpha 2$  domain of HLA-G1.

Art Unit: 1644

Therefore, the instant invention lacks Unity of Invention.

3. **Regardless of whichever group Applicant may elect**, Applicant is further required to (1) elect a single disclosed species of chimeric HLA-E molecule for Group I, or a single disclosed species of nucleic acid molecule encoding a specific chimeric HLA-E molecule for Group II, or a single disclosed species of nonhuman mammalian cell or nonhuman mammalian transgenic animal transformed by the said nucleic acid molecule encoding a specific chimeric HLA-E molecule for Group III, either recited in the instant claims or disclosed in the instant specification, for example, the species of chimeric HLA-E molecule recited in claim 1, part "(1)", wherein all or part of the  $\alpha$ 2 domain of HLA-E is replaced with all or part of the  $\alpha$ 2 domain of HLA-G1, to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different, and a search requires employing different search queries. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply: their structures are different, and a search requires employing different search queries.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Art Unit: 1644

Should Applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

5. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne DiBrino, Ph.D.  
Patent Examiner  
Group 1640  
Technology Center 1600

/G.R. Ewoldt/  
Primary Examiner, Art Unit 1644

